IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re: Metformin Marketing and Sales Practices Litigation	Case No. 2:20-cv-2324-MCA-MAH Honorable Madeline Cox Arleo, District Court Judge Honorable Michael A. Hammer, Magistrate Judge

PHARMACY DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED CONSOLIDATED ECONOMIC LOSS CLASS ACTION COMPLAINT

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INTRODUCTION

Plaintiffs' perfunctory attempt to re-plead their claims following this Court's dismissal neither cures the standing deficiencies identified by this Court nor plausibly states any claim against the Pharmacy Defendants[1] (collectively, the "Pharmacies" or, individually, a "Pharmacy").

In its May 20, 2021 Order dismissing Plaintiffs' claims against the Pharmacies for lack of standing, this Court pointed out two fatal defects in the original Complaint: (1) Plaintiffs failed to allege a cognizable injury because they did not plead that they purchased or ingested any contaminated metformin products; and (2) Plaintiffs failed to trace any purported injury to each named Pharmacy because they did not identify any Pharmacy where they obtained metformin products that allegedly contained NDMA. Dkt. 124, 127.

The First Amended Consolidated Economic Loss Class Action Complaint (Dkt. 128) (the "Amended Complaint") fails to correct either defect. Instead, it is nothing more than a nominal effort to re-plead the same claims with essentially the same allegations that this Court has already held were insufficient to establish standing. Because Plaintiffs still have not established standing, the claims against the Pharmacies should be dismissed.

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[1] The Pharmacy Defendants are CVS Pharmacy, Inc., Rite Aid Corporation, Walgreen Co., and Walmart Inc.

Not only does the Amended Complaint fail to cure the standing defects, but it also fails to cure any of the other pleading defects identified in the Pharmacies' opening motion to dismiss. Specifically, all of Plaintiffs' claims against the Pharmacies are still expressly preempted by the Drug Supply Chain Security Act, which governs the tracing and sourcing of pharmaceutical drugs, including metformin, in the U.S. supply chain. Additionally, Plaintiffs' broad assertions as to all Defendants ignore the unique position of the Pharmacies. Courts do not recognize faultless liability against pharmacies who provide an important healthcare service. Thus, Plaintiffs' warranty claims against the Pharmacies still fail as a matter of law.

Finally, Plaintiffs cannot plausibly claim that the Pharmacies acted negligently, fraudulently, or deceptively, when the Pharmacies simply dispensed a drug that was received from FDA-approved manufacturers with an alleged ***latent*** defect. Nor do Plaintiffs correct their contradictory allegations as to the Pharmacies' alleged knowledge of that defect. Likewise, Plaintiffs still fail to adequately plead a breach of any applicable duty or other wrongful conduct by the Pharmacies, relying only on sweeping, conclusory allegations regarding ***all*** Defendants, with no attempt to differentiate among the numerous entities or even between the Manufacturers and Pharmacies.

For these reasons, and for those argued in the Manufacturers' brief that are incorporated herein, Plaintiffs' claims against the Pharmacies should be dismissed.

PROCEDURAL BACKGROUND

On May 20, 2021, this Court granted the Manufacturers' and Pharmacies' respective Motions to Dismiss the original Complaint. *See generally* Dkt. 124, 127 (the "Order").[2] As to the claims asserted against the Pharmacies, the Court found that Plaintiffs[3] lacked standing because Plaintiffs (1) failed to allege that they suffered a cognizable injury; and (2) failed to connect each Pharmacy's actions to at least one injured Plaintiff by alleging "at which Pharmacy Defendant they purchased their drugs." *Id.* at 3-4. The Court explained that Plaintiffs "failed to demonstrate that they suffered an injury" because they did "not allege[] that they purchased or ingested any [metformin products] containing NDMA." *Id.* at 3. The Court also found that Plaintiffs did "not show[] causation" because they "failed to connect each Defendant['s] actions to at least one injured Plaintiff." *Id.* at 4. As a result, Plaintiffs were granted leave to file an amended pleading "to the extent Plaintiffs can cure the deficiencies identified in [the] order." *Id.* at 5.

[2] This Court granted CVS Pharmacy, Inc.'s Motion to Dismiss, which was joined by Pharmacy Defendants Rite Aid Corporation, Walgreen Co., and Walmart Inc. *See* Dkt. 80, 89, 103, 115. The Motion was originally granted on May 20, 2021 (Dkt. 124), but subsequently amended on June 7, 2021 (Dkt. 127) to expressly include reference to Walmart Inc. and its joinder.

[3] The term "Plaintiffs" as used herein refers to the Consumer Class Plaintiffs, as the Third-Party Payor Class Plaintiffs do not assert any claims against the Pharmacies in the Amended Complaint.

ARGUMENT

I. Plaintiffs' Claims Against the Pharmacies Still Fail For Lack of Standing.

Although Plaintiffs amended their original Complaint, they did so with no regard for this Court's instructions to demonstrate standing to assert their claims. Plaintiffs have failed to cure the deficiencies identified by this Court, and their claims against the Pharmacies must be dismissed, again.[4]

A. Plaintiffs Fail to Plead a Cognizable Injury.

First, this Court held that Plaintiffs failed to plead a cognizable injury because they did "not allege[] that they purchased or ingested any [metformin products] containing NDMA." Order at 3-4. That assertion is still absent in the Amended Complaint. Instead, Plaintiffs rely on the same allegations that each named Plaintiff "bought a product that was not the same as the [Reference Listed Drug]" and which was "illegally and willfully introduced into the market by Defendants"—allegations

[4] Defendant AvKARE Inc. ("AvKARE") joins and adopts arguments made by the Pharmacies in Section I and Section III. AvKARE is a repackager and relabeler, which, like a pharmacy, is situated downstream of the manufacturers in the pharmaceutical supply chain and has no involvement in the manufacturing process at issue. *See* Am. Compl. ¶ 43 (alleging that AvKARE is a repackager and/or relabeler). As such, arguments made by the Pharmacies in Section I are equally applicable to AvKARE, including that Plaintiffs allege no facts that would subject AvKARE to jurisdiction. *See id.* at ¶ 43 (alleging that AvKARE is a Delaware corporation with a principal place of business in Tennessee). Furthermore, Plaintiffs' failure to allege any fault attributable to AvKARE renders baseless the claims sounding in negligence, fraud, violation of consumer protection laws, and unjust enrichment. For the reasons stated in Section III, these claims should be dismissed against AvKARE.

that this Court already found were insufficient in its Order. For this reason alone, Plaintiffs have failed to cure a fatal deficiency in their pleading, and their claims against the Pharmacies must be dismissed.[5]

Additionally, the Court noted that Plaintiffs' economic loss claims relied on the allegation that Plaintiffs paid for metformin products "that were illegally and willfully introduced into the market by Defendants." Order at 2. As the Court previously held, this allegation is insufficient because Plaintiffs do not allege that ***they*** obtained contaminated metformin. *Id.* It is also insufficient to allege a cognizable economic injury, as the Amended Complaint does not allege facts about a diminution in efficacy or any other basis to show that the metformin products were "worthless." Nor do Plaintiffs allege that they themselves were harmed by any allegedly contaminated or recalled metformin. Plaintiffs therefore fail to allege facts "that would permit a factfinder to value the purported injury at something more than zero dollars without resorting to mere conjecture." *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Liab. Litig.*, 903 F.3d 278, 285 (3d Cir.

[5] As explained by the Manufacturers and adopted herein by the Pharmacies, Plaintiffs' failure to allege that they obtained contaminated metformin is not due to "lack of access to relevant information." *See* Manufacturers' Br. at Section II.A.1 (discussing Plaintiffs' ability to ascertain this information through NDCs and public statements). Likewise, any argument that Plaintiffs are not required to plead detailed factual allegations or prove contamination of metformin products at this stage does not relieve Plaintiffs of their obligation to demonstrate that they have standing to assert their claims.

2018) (affirming dismissal where plaintiff failed to "do more than offer conclusory assertions of economic injury"). The Pharmacies further adopt the Manufacturers' arguments on this issue.[6] *See* Manufacturers' Br. at Section II.A.

B. Plaintiffs Do Not Allege an Injury Traceable to Each Pharmacy.

The Amended Complaint not only fails to allege a cognizable injury, but it also fails to sufficiently plead traceability. As this Court recognized, Plaintiffs are required to connect each Pharmacy's "actions to at least one injured Plaintiff" by alleging "at which Pharmacy [] they purchased their drugs." Order at 4. Despite this Court's instructions, the insufficient allegations of Plaintiffs' original Complaint remain largely unchanged and are repeated in the Amended Complaint. *See* Manufacturers' Br. at 5-6 (discussing the four types of substantive revisions made in the Amended Complaint, none of which cure the standing deficiencies).

As to the Pharmacies specifically, Plaintiffs make only one revision to seven paragraphs in the Amended Complaint: Plaintiffs now allege that (1) each named Plaintiff "paid money for one or more" metformin products; (2) those metformin products were "sold in the United States" by certain Manufacturers; and (3) a Pharmacy purchased "[a]t least some" metformin products from those Manufacturers. Am. Compl. ¶¶ 12-18. However, nowhere do Plaintiffs allege that

[6] *PDX North, Inc. v. Asaro-Angelo*, 2019 WL 3416836, at *8 n.9 (D.N.J. July 29, 2019) (permitting adoption and incorporation of another party's arguments).

any named Plaintiff actually obtained a metformin product—let alone metformin contaminated with NDMA—from a specific Pharmacy.[7]

For example, Plaintiffs allege that Joseph Brzozowski paid money for a metformin product manufactured by the Teva Defendants, and that "[a]t least some of this Teva Product . . . was purchased . . . by Retail Pharmacy Defendant CVS." *Id.* at ¶ 12. Plaintiffs never allege that Brzozowski purchased metformin that ***actually*** contained NDMA (*i.e.*, no cognizable injury); never allege that Brzozowski purchased metformin ***from*** CVS (*i.e.*, no traceability); and never allege any combination of those two ***unstated*** (but required) allegations: that Brzozowski purchased metformin that actually contained NDMA from CVS. Nor do any other named Plaintiffs allege that they actually purchased contaminated metformin from any Pharmacy.[8] These allegations are insufficient to establish traceability and cure the deficiencies outlined in this Court's Order.

Similarly, and as set forth in the Pharmacies' opening brief, Plaintiffs allege no facts that would subject any named Pharmacy to jurisdiction in each of the four

[7] *See, e.g.*, Am. Compl. ¶¶ 57, 65, 68, 70 (each named Pharmacy "sold a large portion of the adulterated and/or misbranded [metformin products] to U.S. consumers"); *see also, e.g.*, *id.* at ¶¶ 12-15, 17 ("At least some" of the metformin ultimately purchased by Plaintiffs were purchased from a group of Manufacturers by one Pharmacy Defendant "among other Retail Pharmacy Defendants.").

[8] Plaintiffs make the same convoluted but insufficient allegations regarding Plaintiffs Michael Hahn and Stelios Mantalis (*see* Am. Compl. ¶¶ 13, 15 (Walgreens)), Plaintiff Jacqueline Harris (*see id.* at ¶ 14 (Rite Aid)), and Plaintiff Kristin Wineinger (*see id.* at ¶ 17 (Walmart)).

states where the named Plaintiffs are alleged to reside (California, Indiana, New Jersey, and New York). *See* Dkt. 80 (CVS Motion) at 13-14; *see also* Dkt. 89 (Rite Aid joinder), 103 (Walgreens joinder), 115 (Walmart joinder). Plaintiffs have not pleaded any link between any Pharmacy's activities in those states to any of the named Plaintiffs.

Absent any concrete allegations, Plaintiffs' purported injuries (even if sufficiently pleaded, which they are not) are not traceable to any Pharmacy, and should be dismissed.

C. Plaintiffs Lack Standing to Bring Claims Across Any State.

Even if Plaintiffs had cured the standing deficiencies from their original Complaint, Plaintiffs would ***only*** have standing to assert claims under laws of the states where the named Plaintiffs reside or were allegedly injured—*i.e.*, California, Indiana, New Jersey, and New York. *In re Insulin Pricing Litig.*, 2019 WL 643709, at *17 (D.N.J. Feb. 15, 2019) (dismissal of seventeen counts brought under laws of states in which no named plaintiff resided, and no injury was alleged); *Ponzio v. Mercedes-Benz USA, LLC,* 447 F. Supp. 3d 194, 223 (D.N.J. 2020) (finding class representatives "lack standing to assert claims on behalf of unnamed plaintiffs in jurisdictions where Plaintiffs have suffered no alleged injury"); Am. Compl. ¶¶ 12-18. Yet, the Amended Complaint asserts claims under the laws of ***all*** states, as well as Washington D.C. and Puerto Rico. Am. Compl. ¶¶ 363, 379, 467. As Plaintiffs

do not allege that any named Plaintiffs reside or were injured outside of California, Indiana, New Jersey, and New York, all claims asserted in other states and territories must be dismissed for want of standing.

Although this Court granted leave for Plaintiffs to file an amended pleading with clear instructions to cure the standing defects, Plaintiffs squandered this opportunity and have demonstrated that they cannot sufficiently plead an injury traceable to the Pharmacies to establish standing. They further attempt to improperly bring claims, again, under laws of states where no named Plaintiff resides or was allegedly injured. Any further leave to amend would also be futile because Plaintiffs already had an opportunity to amend with notice of the specific deficiencies to cure in their Amended Complaint. The Pharmacies adopt the Manufacturers' arguments, at Section II.A.1 of their brief, on this point. Therefore, Plaintiffs' claims against the Pharmacies should be dismissed with prejudice for lack of standing, and with no further leave to amend.

II. The Drug Supply Chain Security Act Preempts Plaintiffs' Claims.

Apart from standing, Plaintiffs' claims against the Pharmacies are also preempted by the Drug Supply Chain Security Act (the "Act"), 21 U.S.C. §§ 360eee to 360eee-4, which established a national framework for tracing prescription drugs through the drug supply chain. The claims against the Pharmacies fail as a matter of law because they fall under the Act's express preemption provision.

A. The Drug Supply Chain Security Act Establishes Requirements Governing Pharmacies' Tracing of Drugs.

In 2013, Congress passed the Act in an effort to secure the supply chain for prescription pharmaceutical drugs. 21 U.S.C. §§ 360eee to 360eee-4. The Act is intentionally broad and comprehensive, governing all trading partners in the supply chain for prescription drugs, and establishing a framework of critical steps and "requirements for tracing products" to enable the eventual electronic identification and traceability of prescription drugs. Specifically, the Act states that requirements for tracing products includes, among other things, "any requirements with respect to" (1) "transaction statement[s]," (2) "verification," (3) "investigation," or (4) "recordkeeping." 21 U.S.C. § 360eee-4(a).

In the context of these comprehensive product tracing requirements, the Act imposes specific obligations on pharmacies (*i.e.*, "dispensers"). First, pharmacies may not accept ownership, and must reject shipment, of a prescription drug if the previous owner fails to provide specific information about the drug, including its name, its strength and dose, and the manufacturer's confirmation that the drug is what it purports to be and is fit for distribution. § 360eee-1(d)(1)(A)(i), § 360eee(26)-(27). Second, pharmacies must capture various information "as necessary to investigate a suspect product[,]" including transaction history, product name and dose, and manufacturer's verification of product legitimacy. § 360eee-1(d)(1)(A)(iii). Suspect products include any drug that a pharmacy has actual reason

to believe is potentially counterfeit, intentionally adulterated such that the product would result in serious adverse health consequence or death, the subject of a fraudulent transaction, or otherwise unfit for distribution such that it would cause serious adverse health consequence or death. § 360eee(21). Third, pharmacies must implement a system for quarantining suspect products and investigating whether they are unfit for distribution, in coordination with trading partners. § 360eee-1(d)(4). Through this web of requirements for pharmacies and others in the supply chain, the Act creates a comprehensive, national framework of pharmacies' obligations for identifying, tracing, and isolating adulterated or misbranded drugs. Though Plaintiffs refer to certain provisions of the Act in their Amended Complaint, they do not allege that the Pharmacies failed to comply with the Act.

B. The Act Expressly Preempts All Claims Against the Pharmacies.

To give the Act effect, Congress included a broad express preemption provision that precludes imposition of any state requirement that is "inconsistent with, more stringent than, or in addition to" the Act's requirements, including verification and investigation relating to systems for tracing misbranded or adulterated drugs. 21 U.S.C. § 360eee-4(a). Specifically, no State may establish any requirements for tracing products, including any requirements "with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply

chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems." *Id.* Congress specifically and expressly precluded imposition of any different state law "requirements" which, under well-established Supreme Court precedent, includes requirements set forth under or imposed by common law in individual lawsuits. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 521 (1992); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324-25 (2008).

Plaintiffs' claims fall squarely within the ambit of the Act's preemption clause. Although the Act includes a savings clause in 21 U.S.C. § 360eee-4(c), the clause does not apply here because it simply reiterates the broad scope of the preemption—that is, claims related to the Act's sweeping interpretation of drug tracing (and all of its embedded requirements) are preempted; and any claims unrelated to "product tracing as described in subsection (a)" are not.[9] Not only do

[9] In *In re Valsartan*, Judge Kugler relied heavily on the savings clause in rejecting similar preemption arguments made by pharmacy defendants. *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2020 WL 7418006, at *10-11 (D.N.J. Dec. 18, 2020). Respectfully, Judge Kugler erred in his analysis by ignoring the defining language of the savings clause—"as described in subsection (a)." Judge Kugler's analysis also rests on two further errors: First, the assumption that affording pharmacies preemption under the Act would "ultimately preclude courts from affording state consumers any protection from defective drugs" is simply not true. *Id.* The pharmacies moved for relief under the Act as they are the only entities with relevant obligations under the Act (*e.g.*, accepting product from a manufacturer with transaction information defined by Congress). Additionally, preemption jurisprudence may, in certain circumstances, leave some consumers without a remedy. *E.g.*, *PLIVA v. Mensing*, 564 U.S. 604, 625 (2011) (acknowledging "the unfortunate hand that federal drug regulations has dealt [consumers]"); *Metz v. Wyeth*, 830 F. Supp. 2d 1291, 1294 (M.D. Fla. 2011) ("Tellingly, the Supreme Court

Plaintiffs refer to the Act itself, but the Amended Complaint also specifically invokes the Act's product tracing requirements. *See* Am. Compl. ¶ 335; *see also id.* at ¶¶ 97-102 (discussing the Act's retention requirements). Significantly, Plaintiffs never allege that the Pharmacies violated any of the Act's provisions.

Instead, Plaintiffs rely on the assertion that the Pharmacies have some duty to ensure that a drug labeled "metformin" that has been traced back to an FDA-approved manufacturer is, in its molecular and chemical properties, therapeutically equivalent to metformin. For example, Plaintiffs allege that the Pharmacies warranted that the metformin they dispensed was bioequivalent to metformin's Reference Listed Drug. Am. Compl. ¶¶ 359-61, 382, 401. But Plaintiffs fail to allege any trigger requiring the Pharmacies to investigate and verify the "sameness" of these products in the manner pleaded by Plaintiffs. Without one, the Act requires no such procedure. The Act does not mandate that dispensers test all products, or even identify every misbranded, adulterated, or counterfeit drug—that would be

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in *Mensing* appeared to contemplate that consumers of generic drugs may be without a remedy[.]"). Second, Judge Kugler relied on a presumption against preemption, a doctrine the *Valsartan* plaintiffs had not even invoked. But this Court's "inquiry into the scope of a [federal] statute's pre-emptive effect is guided by the rule that the purpose of Congress is the ultimate touchstone in every preemption case." *Hughes v. Talen Energy Mktg., LLC*, 136 S. Ct. 1288, 1297 (2016) (citing U.S. Const., Art. VI, cl. 2 and *Altria Grp., Inc. v. Good*, 555 U.S. 70, 76 (2008)). Accordingly, no presumption against preemption attaches when an express preemption clause applies, as here. *See Puerto Rico v. Franklin Cal. Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016); *Riegel*, 552 U.S. at 315-30.

impossible. Plaintiffs' claims, if credited, impose product tracing duties upon the Pharmacies that are more stringent than the Act's requirements, and would undermine the balance struck by Congress.

Further, although the Act requires pharmacies to obtain a specific set of information from suppliers as part of its product tracing procedures, it does ***not*** require pharmacies to obtain lists of ingredients and impurities, verify information about the manufacturing process, or demand a guarantee that the product is not adulterated. Plaintiffs' claims, and the duties and warranties Plaintiffs attempt to impose on the Pharmacies, would require the Pharmacies to identify and investigate every single product for "sameness" and safety. This is not what the Act (or Congress) envisions or requires.

In addition to preemption under the Act, Plaintiffs' claims are preempted as invalid attempts to enforce the Federal Food, Drug & Cosmetic Act (the "FDCA") under state law, as explained by the Manufacturers in their brief at Section II.C, which the Pharmacies adopt herein. As such, all of Plaintiffs' claims against the Pharmacies are preempted and should be dismissed.

III. Plaintiffs Fail to State Viable Claims Against the Pharmacies.

Plaintiffs also fail to assert any viable claims against the Pharmacies as a matter of substantive common law.[10]

A. Plaintiffs' Warranty Claims Against the Pharmacies Fail.

Plaintiffs' claims for breach of express and implied warranty should be dismissed as procedurally and facially defective, and because they fail as a matter of law.[11] Courts have widely recognized that pharmacies stand apart from the typical "seller" of a product, and are therefore not subject to warranty liability for latent defects in prescription drugs they dispense. *See Salisbury v. Purdue Pharma, L.P.*, 166 F. Supp. 2d 546, 551 (E.D. Ky. 2001) (noting the "clear national consensus" that pharmacies are not subject to warranty liability); *see also In re Rezulin Prods. Liab. Litig.*, 133 F. Supp. 2d 272, 292 (S.D.N.Y. 2001) (finding that "almost every state that has considered the issue has declined to find pharmacists liable for breach of either implied or express warranty with respect to properties of prescription

[10] The Pharmacies adopt and incorporate herein the arguments in the Manufacturers' brief at Sections II.E-G as to Plaintiffs' failure to adequately plead warranty claims.
[11] For purposes of this Motion, Plaintiffs' claims must be analyzed under the named Plaintiffs' home states: California, Indiana, New Jersey, and New York law. Federal courts apply the choice-of-law principles of the forum state; thus, New Jersey choice-of-law rules apply here. *Chin v. Chrysler LLC*, 538 F.3d 272, 278 (3d Cir. 2008). When confronting a choice-of-law issue, New Jersey utilizes the "most significant relationship" test and applies the law of the state with the most significant relationship to the case and parties. *Grandalski v. Quest Diag. Inc.*, 767 F.3d 175, 180 (3d Cir. 2014).

drugs."). The law, with abundant uniformity, does not recognize warranty liability against pharmacies, and Plaintiffs' warranty claims fail as a matter of law.

1. Plaintiffs' warranty claims against the Pharmacies are procedurally and facially defective.

As an initial matter, Plaintiffs' warranty claims are procedurally defective because Plaintiffs did not provide timely notice to the Pharmacies of any alleged breach before filing suit. This is a condition precedent to their claims.[12]

More significantly, Plaintiffs fail to adequately plead any type of "express" warranty actually made by the Pharmacies. Plaintiffs merely assert that "[b]y selling pharmaceutical drugs in the stream of commerce, each [Pharmacy] warrants that the generic drugs for which they receive payment from are the same as existing brand-named drugs." Am. Compl. ¶ 333. However, "the mere act of selling a [product] by a downstream entity lacking an obligation to comply with the Orange Book formulation," even if the product is determined to be contaminated, "cannot create a bridging argument that translates the sale into an express warranty made by . . . Pharmacies." *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2021 WL

[12] *See Kury v. Abbott Labs., Inc.*, 2012 WL 124026, at *7 (D.N.J. Jan. 17, 2012) (dismissing plaintiff's warranty claim for "fail[ing] to plead that she provided the pre-litigation notice of breach"); N.J. Stat. § 12A:2-607(3)(a); *In re Trader Joe's Tuna Litig.*, 289 F. Supp. 3d 1074, 1092-93 (C.D. Cal. 2017) (same); Cal. Com. Code § 2607(3)(A); *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 544 (S.D.N.Y. 2013) (same); *Courtesy Enters., Inc. v. Richards Labs.*, 457 N.E.2d 572, 579 (Ind. 1983) ("Notice of breach of warranties is a substantive condition precedent to recovery for an asserted breach."); Ind. Code § 26-1-2-607(3)(a).

222776, at *13 (D.N.J. Jan. 22, 2021) (dismissing plaintiffs' express warranty claims against pharmacy defendants). In other words, no express warranty exists merely by virtue of the Pharmacies' dispensing of metformin.

By lumping together all Defendants at every stage of the supply chain, Plaintiffs also assert that each "Defendant" generally warranted that metformin was "not adulterated or misbranded." Am. Compl. ¶ 361. For the reasons explained in the Manufacturers' brief at Section II.F, such vague allegations do not form or constitute an express warranty. *See, e.g.*, *Mladenov v. Wegmans Food Markets, Inc.*, 124 F. Supp. 3d 360, 378 (D.N.J. 2015) (plaintiffs must state the warranty, plead they "saw" it, and "purchased [the product] as a result"). Generic claims of safety also cannot support an express warranty claim. *See, e.g.*, *In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, 588 Fed. Appx. 171, 175-77 (3d Cir. 2014) (noting that courts "have refused to find the words 'safe and effective' to create an express warranty").

Plaintiffs do not allege that the Pharmacies misfilled prescriptions with something other than what manufacturers represented to be metformin. Plaintiffs also do not allege that the Pharmacies urged them to take metformin, made any representation that induced Plaintiffs to choose metformin as their drug of choice, or marketed metformin to Plaintiffs as superior to other available diabetes medications. Finally, no Plaintiff has suggested that any of the Pharmacies made any express

statement that convinced them to take generic metformin manufactured by a specific Defendant over branded Glucophage, or over metformin manufactured by any one of the many other FDA-approved manufacturers not implicated in this litigation. Simply put, there is no basis for finding any cognizable express representation or warranty by the Pharmacies.

2. Plaintiffs' warranty claims fail as a matter of law because the Pharmacies, as dispensers, are not subject to warranty liability under either express or implied warranty theories.

More fundamentally, the Pharmacies are not subject to express or implied warranty liability with respect to the dispensing of prescription medications to patients. Despite Plaintiffs' chosen nomenclature, the Pharmacies do not "sell" prescriptions, but rather, perform a healthcare service by dispensing drugs prescribed by a physician. Warranty claims depend on a seller's status as a merchant of goods. *See* N.J. Stat. § 12A:2-314; N.Y. U.C.C. Law § 2-314; Cal. Comm. Code § 2312; Ind. Code § 26-1-2-104. Prescription drugs are not "goods," and pharmacies, like the Pharmacies here, are not "merchants" under warranty law. Pharmacists, who are extensively trained and regulated, cannot dispense a prescription "except by order of the doctor" and thus are "providing a service to the doctor and acting as an extension of the doctor in the same sense as a technician who takes an X-ray or analyzes a blood sample on a doctor's order." *Murphy v. E. R. Squibb & Sons, Inc.*, 710 P.2d 247, 251 (Cal. 1985); *see also Garza v. Endo Pharms.*, 2012 WL 5267897,

at *2 (C.D. Cal. Oct. 24, 2012) ("Because under California law pharmacies primarily provide a service, not a product, a breach of warranty claim does not lie."); *St. Mary Med. Ctr. v. Casko*, 639 N.E.2d 312, 314 (Ind. Ct. App. 1994) (provision of medical device to patient was service, even if provider acted as a conduit in the distributing the product to the consumer); *Feldman v. Lederle Labs.*, 479 A.2d 374, 380-81 (N.J. 1984) (discussing cases where courts refused to extend faultless liability to dentists and blood banks because "the essential nature of the transaction involves a service").

Relatedly, there is no "bargain" between a pharmacist and a patient who receives a dispensed prescription. The patient relies on the advice of the physician, not the pharmacist, and the "only representations regarding the intrinsic properties of the drug that form the basis of the buyer's purchase are those of the physician." *In re Rezulin*, 133 F. Supp. 2d at 291; *see also In re Valsartan*, 2021 WL 222776, at *13 (dismissal of plaintiffs' express warranty claims against pharmacy defendants for failure to adequately plead the required element of a basis of the bargain). As a New York court explained, "when a consumer asks a druggist to fill a prescription, thus enabling him to obtain a drug which is not otherwise available to the public, he does not rely on the druggist's judgment as to whether that particular drug is inherently fit for its intended purpose but rather he places that confidence and reliance in the physician who prescribed the remedy." *Bichler v. Willing*, 397 N.Y.S.2d 57, 59 (N.Y. App. Div. 1st Dep't 1977); *see also Ingram v. Hook's Drugs,*

Inc., 476 N.E.2d 881, 886 (Ind. Ct. App. 1982) (citing *Bichler* favorably and joining "other jurisdictions which have overwhelmingly held that a pharmacist does not have a duty to warn every customer of the hazards associated with prescription drugs"). Put simply, a "pharmacist's sales of prescription drugs are not attributable to his or her marketing the properties of the drugs. They are attributable to physicians' prescriptions." *In re Rezulin*, 133 F. Supp. 2d at 292.

Imposing liability on pharmacies without fault would undercut the important role they play as adjuncts to the physician-patient relationship. Physicians write prescriptions after weighing the risks and benefits of a drug treatment and the needs of the patient, providing warnings to patients when appropriate. Pharmacies cannot substitute their "judgment of the product's safety for the patient for that of the physician," and requiring a pharmacy to warn a patient of the dangers of a prescribed drug "would have the effect of undermining the physician-patient relationship by engendering fear, doubt, and second-guessing." *Coyle by Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1387 (Pa. 1991); *see also In re Rezulin*, 133 F. Supp. 2d at 288-89 ("A risk averse pharmacist would have every incentive to dispense cautions that may be uninformed, inapplicable to or misunderstood by the patient. Such cautions would be at least as likely to undermine the physician's judgment as manufacturer warnings."); *Ingram*, 476 N.E.2d at 887 ("The injection of a third-

party in the form of a pharmacist into the physician-patient relationship could undercut the effectiveness of the ongoing medical treatment.").

Further, the policy objectives behind the imposition of faultless liability, which Plaintiffs seek to impose through their breach of warranty claims, are inapplicable to the Pharmacies because pharmacies are not in a position to ensure the safety of a physician-directed and FDA-regulated prescription drug. "One of the purposes of imposing strict liability or liability for breach of warranty on retailers is to encourage retailers to pressure manufacturers to make safer products. Yet this goal is lost on pharmacists, who have little or no impact on a manufacturer's marketing of prescription drugs." *In re Rezulin*, 133 F. Supp. 2d at 292; *see also Abrams v. Bute*, 138 A.D.3d 179, 186 (N.Y. App. 2d Div. 2016) ("The responsibility of providing information about the potential hazards of a prescription drug properly falls most heavily on the manufacturer who stands in the best position to recognize and cure defects" (internal quotation marks omitted).). At bottom, "[i]t would be senseless, especially given drug regulation by the Food and Drug Administration and the extensive tort liability of drug manufacturers, to make pharmacies liable in tort for the consequences of failing to investigate the safety of thousands of drugs." *Walton v. Bayer Corp.*, 643 F.3d 994, 1000 (7th Cir. 2011).

The law is clear that it is the manufacturer's responsibility, not the pharmacy's, to manufacture a drug appropriately and to warn of any latent defect.

Otherwise, a pharmacy would be "an absolute insurer" of prescription drugs, subject to the obligation to test each pill it dispenses for latent manufacturing defects. "The costs to society, which needs and values the pharmaceutical products sold by druggists, would be unduly high." *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85, 87 (E.D. Pa. 1986); *see also Winters v. Alza Corp.*, 690 F. Supp. 2d 350, 356 (S.D.N.Y. 2010) (holding that asking "pharmacies [to] ensure the complete safety of any product that they dispense . . . is not only wrong as a matter of law, but it would also impose a duty on pharmacists that is grossly disproportional to their limited degree of expertise[.]").

Accordingly, even if Plaintiffs were able to cure the procedural and pleading defects in their Amended Complaint, any such attempt would be futile because they cannot assert warranty claims against the Pharmacies as a matter of law.

3. The Pharmacies had no knowledge of any alleged NDMA defect and therefore cannot be liable under a warranty theory.

To the extent pharmacies are considered "sellers" of metformin, they cannot be held liable for failing to test for a latent defect—even a manufacturing one—in the drug. Plaintiffs do not plausibly allege that the Pharmacies could have discovered any alleged NDMA contamination. *See, e.g.*, Am. Compl. ¶ 122 (noting "pharmacists . . . can expect such generic drugs to be therapeutically interchangeable" with registered listed drug and not contain impurities). This is fatal to Plaintiffs' warranty claims. Courts have recognized that a pharmacist cannot be

held liable for breach of warranty for a latent defect they "could not have plausibly discovered." *See, e.g.*, *O'Neill v. Std. Homeopathic Co.*, 346 F. Supp. 3d 511, 532 (S.D.N.Y. 2018) (requiring "peculiar knowledge" by retailer); *Cosgrove v. Estate of Delves*, 35 A.D.2d 730, 731 (N.Y. App. Div. 1970) (dismissing warranty claim against retailer because "evidence established that she could not have discovered any danger by mere inspection [and] [s]he was not obligated under these circumstances to . . . test" the product); *see also Levis v. Zapolitz*, 178 A.2d 44, 49 (N.J. Super. Ct. App. Div. 1962) (defendant vendor not liable for failure to make an inspection of a product for latent defects); *Winters*, 690 F. Supp. 2d at 354 ("[A] pharmacist does not have a duty to inspect or test a prescription drug for latent dangers.").

Nor can Plaintiffs circumvent the bar on warranty liability by limiting their claims to economic loss. The policy considerations rejecting implied warranty claims against pharmacies apply equally to personal injury and economic loss claims. It would be senseless to allow such a claim to proceed ***only if*** a plaintiff was ***not*** physically injured. *See O'Neill*, 346 F. Supp. 3d at 532 (dismissing implied warranty claims against retailers predicated on a theory of economic loss).[13]

[13] For the reasons stated in the Manufacturers' brief at Section II.D, Plaintiffs cannot state a claim under the New Jersey Product Liability Act, which governs all claims for harm from a product, precisely ***because*** they allege only economic loss.

4. Courts routinely dismiss similar claims against pharmacies even under a less stringent standard of review.

Even outside the Rule 12 context, numerous courts have found the basis for imposing warranty or other liability on pharmacies to be so tenuous that plaintiffs cannot even meet the fraudulent joinder standard in asserting claims against pharmacies for dispensing FDA-approved prescription drugs. These cases are telling because the fraudulent joinder standard in many courts is more permissive than that applied to a Rule 12(b)(6) motion. *See, e.g.*, *Batoff v. State Farm Ins. Co.*, 977 F.2d 848, 851-54 (3d Cir. 1992) (the inquiry under Rule 12(b)(6) is "more searching than that permissible when a party makes a claim of fraudulent joinder"); *see also Ceballo v. Mac Tools, Inc.*, 2011 WL 4736356, at *5 (D.N.J. Oct. 5, 2011).

Even under the more permissive standard, at least three MDL courts have dismissed pharmacy defendants as fraudulently joined and refused to remand cases back to state court because of an improperly joined pharmacy. *See, e.g.*, *In re Rezulin*, 133 F. Supp. 2d at 291; *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, 692 F. Supp. 2d 1012, 1018-19 (S.D. Ill. 2010), *aff'd sub nom. Walton v. Bayer Corp.*, 643 F.3d 994 (7th Cir. 2011); *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, 2000 WL 1886594, at *4 (E.D. Pa. Dec. 7, 2000). Other district courts in single-claim suits have similarly found pharmacies to be fraudulently joined, holding that there was *"**no possibility that a plaintiff**" **can state a claim*** against those defendants such that

their presence as a party should not defeat diversity. *Hale v. Bayer Corp.*, 2015 WL 5474298, at *3-4 (S.D. Ill. Sept. 16, 2015) (emphasis added).[14]

A theory of liability that cannot survive fraudulent joinder review cannot survive a Rule 12(b)(6) motion. *See Batoff*, 977 F.2d at 852. As such, Plaintiffs' claims, which are no different than those asserted in the cited fraudulent joinder decisions, should be dismissed.

5. Plaintiffs' Magnuson-Moss Warranty Act claims fail.

Further, as argued in the Manufacturers' brief at Section II.G, Plaintiffs' Magnuson-Moss Warranty Act ("MMWA") claims also fail. First, the MMWA prohibits warranty claims involving FDA-regulated items. 15 U.S.C. § 2311(d) (MMWA does not apply to "any written warranty the making or content of which is otherwise governed by Federal law."); *see also In re Valsartan*, 2021 WL 222776, at *21 (dismissing plaintiffs' claims for violations of MMWA). Second, Plaintiffs have not satisfied the MMWA requirement that they afford the Pharmacies a "reasonable opportunity to cure" any purported failure to comply with a warranty. 15 U.S.C. § 2310(e). Finally, given that a MMWA claim is derived entirely from

[14] *See also, e.g.*, *Duckett v. SCP 2006-C23-202, LLC*, 225 F. Supp. 3d 432, 436 (D.S.C. 2015); *Smith v. Wyeth, Inc.*, 488 F. Supp. 2d 625, 629-30 (W.D. Ky. 2007); *Sanks v. Parke-Davis*, 2000 WL 33910097, at *4-5 (M.D. Ala. Oct. 30, 2000); *Oshima v. Kia Motors Corp.*, 2012 WL 1578397, at *5-7 (D. Colo. May 4, 2012); *Baymiller v. Ranbaxy Pharms. Inc.*, 2012 WL 2727874, at *5 (D. Nev. July 9, 2012); *White v. Mylan, Inc.*, 2012 WL 6726593, at *3 (W.D. Okla. Dec. 27, 2012); *Thomas v. Wyeth*, 2005 WL 3754203, at *3 (S.D. W. Va. June 16, 2005).

state warranty law, Plaintiffs' failure to establish a breach of implied or express warranty claim under any state law is equally fatal to their MMWA claim. *See, e.g.*, *Johansson v. Cent. Garden & Pet Co.,* 804 F. Supp. 2d 257, 265 (D.N.J. 2011) (dismissing MMWA claim where underlying state claim was dismissed).

For all of these reasons, as well as the arguments made by the Manufacturers with respect to warranty claims (except as to privity), Counts 1, 3, and 5 of the Amended Complaint should be dismissed against the Pharmacies.

B. Plaintiffs Have Not Pleaded Grounds to Hold the Pharmacies Liable for Negligence.

Plaintiffs' claims for negligence (Counts 15 and 17) and negligent misrepresentation (Count 9) likewise fail and should be dismissed for multiple reasons.[15] At the outset, the Pharmacies adopt and incorporate by reference the Manufacturers' arguments at Sections II.B and II.H-I regarding Plaintiffs' "shotgun"

[15] Additionally, unjust enrichment in Indiana requires "proof that defendants' actions were wrongful and/or not justified," essentially imposing a negligence standard. *See In re AT&T Fiber Optic Cable Installation Litig.*, 2001 WL 1397295, at *12 (S.D. Ind. Nov. 5, 2001). In New York, "a valid claim for unjust enrichment can only be based upon 'an element of misconduct or fault, or undue advantage taken by one party of another.'" *F. E. Grauwiller Transp. Co. v. King*, 131 F. Supp. 630, 634 (E.D.N.Y. 1955) (dismissing unjust enrichment claim because there was no evidence of misconduct, fault, or undue advantage). In California, "unjust enrichment is a remedy that cannot stand alone apart from a substantive allegation of misconduct." *Baba v. Hewlett-Packard Co.*, 2010 WL 2486353, at *9 (N.D. Cal. June 16, 2010). Thus, in addition to the reasons in *infra* Section III.E, Count 13 should be dismissed for claims arising under Indiana, New York, and California law for the reasons discussed herein relating to negligence.

allegations and claims for negligence and negligent misrepresentation, which fail to meet the pleading standards of Rules 8 and 9(b).[16] Additionally, Plaintiffs have not pleaded, and cannot plead, that the Pharmacies breached any duty allegedly owed to them, their negligence claims must therefore be dismissed.

1. Plaintiffs have not pleaded professional negligence.

For the same reasons pharmacies are not subject to strict or warranty liability, pharmacies are also not subject to negligence claims unless they are professionally negligent in a malpractice type of action. Plaintiffs have not pleaded any type of professional negligence here. Again, any defect in metformin was latent, and no amount of reasonable care could have identified that alleged defect to the Pharmacies. In fact, Plaintiffs' negligence claims even contradict their own allegation that pharmacies, like Plaintiffs themselves, can rely on FDA's approval and the manufacturers' affirmations of sameness. Am. Compl. ¶ 122 ("Pharmacists,

[16] The relationship between the Pharmacies and their pharmacy customers does not meet the required element of a negligent misrepresentation claim under New York law. *See, e.g.*, *Pure Diets India Ltd. v. Genco*, 2019 WL 428834, at *7 (S.D.N.Y. Feb. 4, 2019) (dismissing plaintiff's negligent misrepresentation claim because a "relationship . . . typical of an arm's length transaction . . . is insufficient to support a negligent-misrepresentation claim); *Foxley v. Sotheby's Inc.*, 893 F. Supp. 1224, 1232 (S.D.N.Y. 1995) ("An 'arm's length business relationship is not enough."). In any event, ***the Pharmacies*** did not make any representations to Plaintiffs here. *See, e.g.*, *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 219 (E.D.N.Y. 2004) ("Absent any allegation that [the pharmacy] affixed the label, which contained the alleged misrepresentation, to the counterfeit [drug], plaintiff cannot state a claim for negligent misrepresentation against [the pharmacy].").

physicians, and patients can expect [FDA-approved] generic drugs to be therapeutically interchangeable[.]").

Plaintiffs' failure to allege the patency of any defect distinguishes this case from cases alleging professional malpractice.[17] Here, there is no dispute that the metformin at issue was authentic and manufactured by FDA-approved generic drug manufacturers. Am. Compl. ¶¶ 280-83. Plaintiffs cannot identify any patent defect in the metformin that would have enabled the Pharmacies to identify the drug as problematic. The alleged contamination in metformin was found only after FDA developed a unique analytical method to test for it in 2018, after allegations regarding NDMA contamination arose in another drug, valsartan. "Because it was not anticipated that NDMA would occur at these levels," FDA scientists observed, even "manufacturers would not have been testing for it."[18] The latent nature of the alleged defect, and the difficulty that FDA noted in even identifying the alleged

[17] For example, in *Fagan*, the plaintiff alleged that the defendant pharmacy shipped a counterfeit drug to plaintiff ***after*** its particular lot number had been publicly identified as being counterfeit and that it could have identified it as counterfeit before it was publicly identified as such, because a basic inspection of the label revealed that it had different markings than the authentic drug shipped by the FDA-approved manufacturer. *Fagan*, 356 F. Supp. 2d at 204, 213.

[18] *See* Scott Gottlieb and Janet Woodcock, FDA Statement on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings (Aug. 30, 2018), https://www.fda.gov/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-impurities-and-recalls-and-update-fdas-current.

impurity, distinguish this from patent defect cases like *Fagan*, and underscore why dismissal is appropriate in this case.[19]

2. Pharmacies have no duty to test or inspect prescription drugs.

Plaintiffs' negligence claims also fail because they cannot plead that the Pharmacies breached any duty owed to them. Every "fault-based" allegation against the Pharmacies is premised on an alleged failure to test or inspect prescription drugs, but Plaintiffs cannot point to any law—because there is none—suggesting that pharmacies have a duty to test prescription drugs. *See Winters*, 690 F. Supp. 2d at 354 ("[A] pharmacist does not have a duty to inspect or test a prescription drug for latent dangers."). A plaintiff cannot "recover in negligence on the hypothesis that [the pharmacy] dispensed the drug without first inspecting or testing it for the purpose of discovering its latent dangers." *Bichler*, 397 N.Y.S.2d at 58; *see also Ullman v. Grant*, 450 N.Y.S.2d 955, 956 (Sup. Ct. 1982); *Abrams*, 27 N.Y.S.3d at 71. As held by the Sixth Circuit in affirming judgment for a pharmacy, there "is no law to support [the] assertion" that a pharmacy has "[a] duty to investigate and test

[19] With respect to those claims arising under California law, Plaintiffs' claims also fail because Plaintiffs have failed to provide pre-suit notice as required under Cal. Civ. Pro. § 364. *E.g., Ambriz v. CVS Pharm., Inc.*, 2020 WL 1660018, at *2-3 (E.D. Cal. Apr. 3, 2020); *see also Garza*, 2012 WL 5267897, at *2 (dismissing negligence claims because plaintiffs did not plead facts demonstrating how pharmacy "was allegedly involved in the purported mispackaging or mislabeling" of medication).

any prescription medications it sold before dispensing them to customers." *Flint v. Target Corp.*, 362 F. App'x 446, 448-49 (6th Cir. 2010).

This basic premise is supported more generally by the overwhelming weight of authority holding that a vendor has no duty to inspect or test a product manufactured by another for latent defects. *See, e.g.*, *Oddi v. Ford Motor Co*., 234 F.3d 136, 143-44 (3d Cir. 2000) (finding that plaintiff "cited no authority that establishes the principle that a manufacturer has a general duty to test its product. We have found no authority to support . . . an independent tort for 'negligent failure to test,' and [plaintiff] has offered none").[20]

Similarly, Plaintiffs cannot merely plead that a duty exists without any factual support. In the Zantac MDL, also involving allegedly defective pharmaceuticals, the court recently dismissed negligence claims against the pharmacy defendants because (among other reasons) the plaintiffs' argument would require accepting that the standard, routine practices of every pharmacy were faulty and that "each day thousands of companies commit ordinary negligence." *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 2021 WL 2685605, at *10 (S.D. Fla. June 30, 2021). Noting that

[20] *See also, e.g.*, *Levis*, 178 A.2d at 49 (no liability of defendant vendor for failure to make an inspection of a product for latent defects); *Stump v. Ind. Equip. Co., Inc.*, 601 N.E.2d 398, 406 (Ind. Ct. App. 1992) (finding that equipment dealer had no duty to inspect and discover latent defects, only patent ones); *Noveck v. PV Holdings Corp.*, 742 F. Supp. 2d 284, 299 (E.D.N.Y. 2010) ("[W]hen a defect is discoverable only by special tests or by an expert's examination, a retailer will generally not be liable for failure to discover" (internal citations omitted).).

the plaintiffs had provided "no citation" to the law of any jurisdiction supporting their theory, and that the plaintiffs' response was "silent" to the defendants' arguments regarding the impact of their liability theory, the court declined to create a new standard of care that would have required sweeping industry change. *Id.* The same is true here.

Plaintiffs' constructive knowledge allegations are further insufficient to support a negligence claim. Their attempt at circumventing their failure to establish that the Pharmacies had some sort of distinct duty in dispensing metformin comes by way of a vague assertion that the Pharmacies "should have known" of the alleged NDMA impurity. This is insufficient to save their negligence claims.

First, this allegation is contradicted by Plaintiffs' contention that the manufacturers concealed the presence of NDMA in their metformin products. The Pharmacies did not know and could not have known the manufacturers were, as alleged, "tr[ying] to conceal or destroy the evidence" of the products' "contamination with NDMA." Am. Compl. ¶ 270.[21] The Zantac MDL court addressed similar allegations, rejecting the plaintiffs' argument that they sufficiently

[21] Notably, the Manufacturers deny they concealed any NDMA contamination, and in fact argue that Plaintiffs' other allegations, that the Manufacturers "would have" identified nitrosamine contaminants had they adhered to cGMPs, indicate that the Manufacturers did ***not*** know of the contamination due to the use of the past modal tense. *See* Manufacturers' Br. at Section II.H.3. Regardless, Plaintiffs have offered ***nothing*** to support the idea that the Pharmacies had any knowledge of the potential for NDMA contamination within metformin.

pleaded that the pharmacy defendants had knowledge of the alleged defect because the plaintiffs, like Plaintiffs here, alleged that only the manufacturers had knowledge of the dangers of the drugs. *In re Zantac*, 2021 WL 2685605, at *7.

Second, setting aside this material contradiction, vague assertions as to what the Pharmacies "should have known," without additional facts demonstrating their knowledge of the presence of NDMA in metformin products, fail to satisfy fundamental pleading requirements. Formulaic recitations of the elements of a claim "will not do." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Butera v. Honeywell Int'l*, 2020 WL 64568, at *7 (D.N.J. Jan. 6, 2020) (pleadings failed to "allege any facts to support a finding that membership in the industry gave Defendant actual or constructive knowledge" of defect); *Giles v. Wal-Mart La. LLC*, 2016 WL 2825778, at *6 (E.D. La. May 13, 2016) ("Plaintiff's bald assertion that all Defendants had actual or constructive knowledge of the allegedly defective condition is a conclusory allegation that the Court is not required to accept.").

Even under the more permissive fraudulent joinder standard, courts routinely reject conclusory allegations regarding actual or constructive knowledge in cases involving pharmacists dispensing prescription drugs where, as here, the complaint simultaneously alleges concealment of the information by the manufacturing co-defendants. This is because the "impossibility of the claim" against the pharmacy "is implicit in the contradictory allegations . . . . In each of these cases, the premise

of the case against the non-diverse defendant(s) that they knew or should have known of the dangers is undercut, defeated, and made impossible by the claims of fraud and misrepresentation against the manufacturers." *Baisden v. Bayer Corp.*, 275 F. Supp. 2d 759, 762-63 (S.D. W. Va. 2003).

Other courts likewise have rejected "bald allegations" of negligence against pharmacies in the fraudulent joinder context. *See In re Avandia*, 624 F. Supp. 2d at 424 (failure "to use reasonable care" in selling prescription drug was too conclusory to state a claim) (quoting *Locicero v. Sanofi Aventis U.S., Inc.*, 2007 WL 7117880, at *3 (W.D.N.Y. Nov. 7, 2007)); *see also In re Diet Drugs*, 2004 WL 1925010, at *1 (dismissing pharmacy defendant because complaint fell "far short" of alleging the pharmacy knew or should have known the dangers of prescription). Applying even the more permissive pleading standard warrants dismissal of Plaintiffs' negligence claims against the Pharmacies.

C. Innocent Seller Statutes Protect the Pharmacies from Liability.

In addition, to the extent that Plaintiffs attempt to state a claim through the state product liability acts in New Jersey or Indiana (whether labeled as negligence, breach of warranty, or unjust enrichment—*see* Manufacturers' Br. at Section II.D-E), their claims fail because New Jersey and Indiana statutorily immunize innocent sellers like the Pharmacies here. *See* N.J. Stat. § 2A:58C-9; Ind. Code § 34-20-2-3.

Although New Jersey's law requires submission of an affidavit identifying the manufacturer, that rule is procedural, not substantive, and thus not a barrier to dismissal under Rule 12(b)(6) in federal court. *See Hanna v. Plumer*, 85 S. Ct. 1136, 1141 (1965) (holding generally, "federal courts are to apply state substantive law and federal procedural law"); *see also Crosby v. Georgakopoulos*, 2005 WL 1514209, at *7 (D.N.J. June 24, 2005) (granting motion to dismiss where defendant was clearly not the manufacturer of the product at issue). Here, the Manufacturers are present and Plaintiffs are pursuing their claims against them. To the extent the product liability acts apply, Plaintiffs cannot state claims against the Pharmacies because the Pharmacies did not manufacture metformin or have any responsibility for its design, manufacture, labeling, or alleged defect.

D. Plaintiffs' Fraud and State Consumer Protection Claims Also Fail.

The foregoing discussion of the deficiencies in Plaintiffs' pleadings also makes clear that Plaintiffs' claims of fraud (Count 7) and violation of state consumer protection statutes (Counts 11, 19, 20, 21, 22) cannot pass muster. Because Plaintiffs rely on alleged fraudulent activity or misrepresentation as a basis for asserting liability, each of Plaintiffs' misrepresentation and consumer protection claims must be pleaded with sufficient particularity under Rule 9(b). *Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 85 n.3 (3d Cir. 2015); *see also Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 629 (4th Cir. 2008) ("Rule 9(b) refers to 'alleging

fraud,' not to causes of action or elements of fraud. When a [party] makes an allegation that has the substance of fraud, therefore, he cannot escape the requirements of Rule 9(b) by adding a superficial label[.]"); *see also* Manufacturers' Br. at Section II.H.1 (cases showing that consumer protection claims sound in fraud).

For the reasons stated in the Manufacturers' brief at Section II.H and adopted herein, Plaintiffs fail to articulate any type of fraud against any Defendant, much less the Pharmacies. Plaintiffs do not allege that the Pharmacies committed any fraudulent or deceptive act—only (and tenuously) that they dispensed metformin, received from FDA-approved manufacturers and which Plaintiffs admit contained a latent defect.

To the extent Plaintiffs attempt to articulate actual activity or misrepresentations that form the basis of their claims, they do so with vague and conclusory statements regarding all "Defendants," without differentiation as to the roles or actions of any specific entity in the supply chain, such that the allegations are indistinguishable and fail to put each of the Defendants on notice of the roles they played in any allegedly fraudulent scheme. *See In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, 2021 WL 307486, at *15 (D.N.J. Jan. 29, 2021) (dismissing plaintiffs' fraud claims against pharmacies because, among other reasons, their "[c]ollectivized allegations against 'defendants' do not put each defendant on notice of the roles they each played in the alleged scheme," which

"failure is detrimental to plaintiffs' fraud claim because notice is the main purpose of Rule 9(b)'s particularity requirement" (internal citations omitted)); *Montero v. Teva Pharms. USA Inc.*, 2020 WL 1862593, at *4 (S.D.N.Y. Apr. 14, 2020) (dismissing plaintiff's fraud claims for failure to "differentiate between Defendants, much less identify a particular speaker or the person responsible for the failure to disclose"); *Weske v. Samsung Elecs., Am., Inc.*, 934 F. Supp. 2d 698, 703 (D.N.J. 2013) (dismissing plaintiff's fraud and consumer protection claims against manufacturer and seller for failure to differentiate between the defendants and plead sufficient facts of "who, what, when, where, and how" and noting that "[a]wareness of a few customer complaints . . . does not establish knowledge of an alleged defect"); *Roche Diagnostics Corp. v. Binson's Hosp. Supplies, Inc.*, 2017 WL 4123050, at *8 (S.D. Ind. Sept. 18, 2017) (dismissing plaintiff's fraud claims for improperly grouping multiple defendants together and "failing to sufficiently state who made each allegedly fraudulent misrepresentation" and "fail[ing] to identify the time, place, content, or method of communication used for the defendants' allegedly fraudulent misrepresentations").

Moreover, Plaintiffs' allegations fail to identify any particular details of the alleged fraud—no time, place, content of any statement or misrepresentation by the Pharmacies as may relate to any individual Plaintiff's purported purchase of metformin—and do not inject precision or a measure of substantiation into their

allegations. *See e.g.*, *In re Valsartan*, 2021 WL 307486, at *15 (dismissing fraud claims against pharmacies). Even if there was any modicum of specificity as to the Pharmacies' actions, Plaintiffs could not plead a viable basis for the misrepresentation element of their claims. Any claims seeking to impose liability because of a purported misrepresentation that metformin complied with FDA requirements, or was bioequivalent to the branded equivalent or Reference Listed Drug, are preempted by federal law. *See* Manufacturers' Br. at Section II.C. Even according to Plaintiffs' own pleading, any duty relating to bioequivalence falls squarely on metformin's manufacturers, not dispensing pharmacies dispensing. *See* Am. Compl. ¶¶ 112, 281 (manufacturers, not pharmacies, make warranties of bioequivalence). The Pharmacies cannot have breached a duty they did not owe, and any attempt to impose liability here is preempted by federal law.

In addition to the numerous pleading deficiencies of Plaintiffs' state law consumer protection claims, as articulated in the Manufacturers' brief at Section II.H, Plaintiffs' claims also fail because the Pharmacies' act of dispensing prescription medication is not a "consumer-oriented practice." *Amos v. Biogen Idec Inc.*, 28 F. Supp. 3d 164, 173-74 (W.D.N.Y. 2014) (dismissing plaintiff's consumer protection claims because "defendants' alleged deceptive practice of failing to provide adequate warnings by concealing information is not, as a matter of law, a practice directed at consumers"); *accord Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d

514, 522 (E.D. Pa. 2006) ("securities and prescription drug labeling are highly regulated by the federal government . . ., like securities, prescription drugs are not available in the same manner as usual consumer products") (applying New York law), *aff'd on other grounds*, 521 F.3d 253 (3d Cir. 2008) (preemption), *vacated on other grounds*, 556 U.S. 1101 (2009) (preemption); *Kanter v. Warner-Lambert Co.*, 99 Cal. App. 4th 780, 797-98 (2002) ("[A] drug regulated by the [Federal Food, Drug, and Cosmetic Act] is . . . not a consumer product . . . .").

Plaintiffs have also not pleaded any cognizable basis for claiming that the Pharmacies engaged in deceptive or unjust acts. Rather, Plaintiffs seek to impose liability on the Pharmacies for failure to warn about an alleged latent defect that the Pharmacies did not know and could not have known about. Am. Compl. ¶¶ 443, 444, 482. Plaintiffs' consumer protection claims against the Pharmacies represent a dramatic and unprecedented form of liability that, research suggests, has never before been permitted. *See Carrozza v. CVS Pharm., Inc.*, 391 F. Supp. 3d 136, 149-50 (D. Mass. 2019) (holding no basis for a claim of unfair or deceptive business practices against CVS); *Altieri v. CVS Pharm., Inc.*, 2002 WL 31898323, at *4-5 (Conn. Super. Ct. Dec. 13, 2002) (finding that pharmacy provided a service and was subject to negligence claims for misfiling prescriptions but not to consumer protection claims); *Ruiz v. Walgreen Co.*, 79 S.W.3d 235, 238-39 (Tex. App. 2002) (dismissing plaintiff's Deceptive Trade Practices Act claim against pharmacy);

Strong v. Merck & Co. Inc., 2009 WL 7233281 (Ariz. Super. Nov. 9, 2009) ("[P]rescription drugs are not a 'product' under Arizona's Consumer Fraud Act.").

To allow these claims to go forward would "require[] every pharmacist to act as a sort of shadow FDA, making decisions about what types of drugs are and are not safe for the public as a general matter. There is simply no reason to believe that pharmacists are—or should be—equipped to make those sorts of decisions, and asking them to do so would entail a dramatic expansion of their duties[.]" *Winters*, 690 F. Supp. 2d at 356 (granting pharmacy's motion for judgment on the pleadings).

E. Plaintiffs' Unjust Enrichment Claim Fails As A Matter of Law.

Finally, Plaintiffs' unjust enrichment claim (Count 13) fails for the reasons set forth above and discussed by the Manufacturers. *See* Manufacturers' Br. at Section II.J (dismissal of unjust enrichment claim is warranted where other adequate remedies at law are available and the claim relies on the same allegations that form the basis of their other claims). The Pharmacies provided a service of dispensing metformin, as obtained from FDA-approved manufacturers, to patients with a prescription for it from their physicians. Plaintiffs do not allege that the Pharmacies failed to provide that service, and the Pharmacies have not been enriched unjustly. To hold otherwise would upend product liability law and demonstrate an unprecedented departure from statutory and common law protections for pharmacies and similar entities.

As Plaintiffs' claim for unjust enrichment fails, their requested remedy of disgorgement of profits, tied only to their unjust enrichment claim, is similarly doomed. Further, this extraordinary remedy is only appropriate where a tortfeasor's "conscious wrongdoing" requires it. *See* Restatement (Third) of Restitution and Unjust Enrichment § 3 cmt. a (Disgorgement of profits is "limited to cases of . . . 'conscious wrongdoing,' because the disincentives that are the object of a disgorgement remedy are not required in dealing . . . with inadvertent tortfeasors."). A "'conscious wrongdoer' is a defendant who is enriched by misconduct and who acts (a) with knowledge of the underlying wrong to the claimant, or (b) despite a known risk that the conduct in question violates the rights of the claimant." *Id.* § 51.3. Plaintiffs cannot allege that the Pharmacies acted with conscious wrongdoing, and their request for disgorgement is misdirected.

CONCLUSION

For the foregoing reasons, as well as those reasons applicable to the Pharmacies as outlined in the Manufacturer Defendants' brief, the Pharmacy Defendants respectfully request the dismissal of all claims against them.

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Respectfully submitted,

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